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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
REDDICK, MARIE L	

ART UNIT	PAPER NUMBER
1713	

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/720,190	VORLOP ET AL.	
	Examiner	Art Unit	
	Judy M. Reddick	1713	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/21/04 & 11/15/04*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 21-31* is/are pending in the application.

4a) Of the above claim(s) *25-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19, 21-24 & 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The Amendment filed on 11/15/04 is sufficient to overcome the Rejection under 35 USC § 112, first paragraph as applied to claims 2, 3, 7 & 8 (04/23/04, paragraph no. 4) and the Rejection under 35 USC § 112, second paragraph as applied to claims 2, 3, 7, 8 and 13-15 (04/23/04, paragraph no. 6).

Election/Restrictions

2. Claims 25-30 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As far as the Examiner can tell, no support can be found for the limitations recited per new claim 31 and this, as such, without any guidelines from applicant as to where support might be found, engenders a New Matter situation.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-19, 21-24 & 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charmot et al (U.S. 4,737,533).

Charmot et al disclose dry material which can be hydrated into an aqueous gel comprising (1) a matrix comprising a macromolecular substance A which includes proteins, capable of forming a porous aqueous gel when it is in the presence of water, (2) a water-soluble linear polymer B which includes polyethylene glycols governed by a weight average molecular weight of about 1,000 and polyvinyl alcohol, (3) a plasticizer for the macromolecular substance A which includes polyethylene glycols having a weight average molecular weight of less than 400 and, (4) dispersed in the matrix, particles of a polymer C obtained from at least one water-immiscible monomer. Charmot et al further teach that the antecedently recited material can be obtained by mixing an aqueous solution of macromolecular substance A with the polymer B, the plasticizer and a latex of polymer C, followed by cooling, shaping and drying of the aqueous gel obtained. The dry material can be used in biological applications after rehydration. Charmot et al, @ col. 4, lines 39 – 52, teach that polymer C may be "sensitized" which means that biologically active substances such as antibodies, antigens, drugs and enzymes are immobilized on the particles of polymer C and that the particles of polymer C included in the matrix are polymer particles which can be magnetized. More specifically, Charmot et al @ col. 5, lines 2-40 teach that the dry material which can be hydrated is obtained via (1) mixing (a) an aqueous solution of a macromolecular substance A capable of forming, after preferably cooling to a temperature of 30 to 80 degree C, a porous aqueous gel when the substance A is in the presence of water, at a preferred concentration of the substance A effective for forming the gel at a temperature of 30 to 80 degrees C, (b) a water-soluble linear polymer B, (c) a plasticizer for the macromolecular substance A, and (d) a latex of a polymer C and wherein mixing occurs at a temperature greater than the gelling temperature of the aqueous solution of the macromolecular substance A; 2) cooling the resultant mixture to a temperature less than the gelling temperature of the aqueous solution of the macromolecular substance A and shaping the aqueous gel obtained during the cooling wherein, the shaping process consists of pouring the mixture obtained in the mixing stage onto a support consisting of a transparent thermoplastic plate which is placed on a horizontal glass plate, allowing the mixture to cool to form an aqueous gel which adheres to the plate, and covering the aqueous gel film with a regenerated cellulose-based sheet soaked in an aqueous solution of glycerol wherein the sheet of regenerated cellulose is folded back under the glass plate and (3) drying the shaped aqueous gel at a temperature less than the gelling temperature of the aqueous solution of the macromolecular

substance A. Charmot et al @ col. 6, lines 46-66 also teach that a gel in the form of a film may be obtained by pouring the mixture on a glass plate and allowing it to cool to convert the liquid film deposited into an aqueous gel film. The aqueous gel film may then be demolded and dried. Lastly Charmot et al @ col. 7, lines 3-22 teach that the product is particularly valuable for its uses in biological applications, the porous nature of the gel of the macromolecular substance A enables proteins to reach the particles of polymer C and to become bound thereto by absorption or covalency and the dry material which can be hydrated into an aqueous gel containing dispersed polymer particles and has the advantage of combining the positive properties of the matrix, i.e., of being (1) capable of being hydrated at the desired time into a porous aqueous gel in such forms as films, plates, sticks, pellets and beads which can be easily handled, (2) compatible even with aqueous media with high concentrations of electrolytes, and (3) permeable to high molecular weight proteins, with the positive properties of the polymer particles derived from a water-immiscible monomer, viz. having a high and controlled specific surface area and a wide range of available chemical groups on the surface. See, e.g., the Abstract, cols. 1, 2, 4-7, the Runs and claims of Charmot et al.

The disclosure of Charmot et al differs basically from the claimed invention as per the non-specificity relative to the polyvinyl alcohol component, as claimed. However, the "polyvinyl alcohol" component per Charmot et al is generic to the claimed "polyvinyl alcohol" component and necessarily implies that any "polyvinyl alcohol", including the claimed "polyvinyl alcohol" would have been operable within the scope of patentees invention and with a reasonable expectation of success. Moreover, the use of any commercially available polyvinyl alcohol component in lieu of the polyvinyl alcohol component of Charmot et al would have been obvious to the skilled artisan and with a reasonable expectation of success, criticality for such, commensurate in scope with the claims, not have been demonstrated on this record. Moreover, as to the content of water removal, although generic, such is a necessary implication that any water content removal, including the claimed content of water removal, would have been operable within the scope of patentees invention and with a reasonable expectation of success, absent a clear showing of unexpected results, commensurate in scope with the claims. While Charmot et al do not expressly recognize the generation of a "bio-catalyst" from the disclosed process, motivation in the prior art does not have to be the same as that for the claimed invention as provided for under the guise of In re Kemps, 30 USPQ2d 1309(Fed. Cir. 1996). Moreover, the formation of the here recited bio-catalyst would merely follow as a necessary incident to the selection of the recited steps based solely on the motivation or suggestion provided in Charmot et al. It would be reasonably expected that a phase separation of the polyvinyl

alcohol solution of Charmot et al, as modified, would occur since the process parameters and components of Charmot et al, as modified, are essentially the same as the claimed process parameters and components and in the absence of the USPTO to have at its disposal the tools and facilities deemed necessary to make physical determinations of this sort. As to the sequence of steps, the selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results (In re Burhans, 154 F.2d 690, 69 USPQ, 330 (CCPA 1946) & Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959)).

As to the remaining process parameters of the dependent claims, the limitations are either taught by Charmot et al, suggested by Charmot et al or would have been obvious to the skilled artisan and with a reasonable expectation of success. More specifically, any additional or particular claim parameters that may not be specifically set out in the references are considered not to involve anything unobvious absent a showing to the contrary.

Claim Rejections - 35 USC § 103

7. Claims 1-19, 21-24 & 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venkatraman et al (U.S. 6,039,977).

Venkatraman et al teach pharmaceutical formulations. More particularly, Venkatraman et al teach pharmaceutical hydrogel formulations containing polyvinyl alcohol, water, a therapeutically effective amount of a drug and other additives which are useful in a variety of contexts, including electrotransport drug delivery, methods for making the formulations, electrotransport drug delivery systems containing the hydrogel formulations as drug reservoirs and methods for substantially eliminating syneresis in a polyvinyl alcohol hydrogel system, said method involving selecting a degree of hydrolysis and corresponding percent by weight of polyvinyl alcohol in the gel that is effective in forming a hydrogel which is stable to syneresis. In making the formulations, Venkatraman et al teach that the method entails dissolving a predetermined amount of polyvinyl alcohol in an aqueous liquid, combining the polymer solution with a therapeutically effective amount of drug and other additives, and gelling the solution by a freeze-thaw process in which thawing is conducted for a time period of 5 hours or less. The resultant hydrogel is mechanically strong and stable to syneresis. The formulation may be used to form a drug reservoir for passive transdermal drug delivery or for electrotransport drug delivery. Venkatraman et al further teach that alternatively, the formulation may be combined with a pharmaceutically acceptable carrier suitable for other modes of drug administration wherein, suitable carrier

materials include, inter alia, polyethylene glycol(sufficient to meet the additive b) per the claimed invention). More specifically, Venkatraman et al teach that an alternative method for incorporating the drug and other desired additives into the hydrogel involves forming the gel in the absence of drug, removing the water(dehydrating), and hydrating the gel with an aqueous drug solution containing the other desired additives. Venkatraman et al teach that this method is particularly useful for drugs and/or formulation additives that are heat-sensitive. Most specifically, Venkatraman et al @ col. 9, lines 1+ teach that the invention is also useful in conjunction with the electrotransport delivery of proteins, peptides and fragments thereof(sufficient to meet the biologically active material c) per the claimed invention), whether naturally occurring, chemically synthesized or recombinantly produced. See, e.g., the Abstract, col. 1, lines 1-15. col. 3, lines 29-67, col. 4, lines 1-67, col. 5, lines 6-65 and cols. 6-9 of Venkatraman et al. In terms of the polyvinyl alcohol component of the hydrogel, Venkatraman et al @ least at col. 5, lines 56+ teach that the percent by weight of polyvinyl alcohol in the hydrogel, Y, is selected to correspond to the degree of hydrolysis of the polymer, Dh. When the Dh is in the range of approximately 95% to 99.9%, Y is in the range of approximately 10 wt. % to 30 wt. % and preferably, in the range of approximately 96% to 99% and Y is in the range of approximately 12 wt. % to 25 wt. %, sufficient to meet the limitations per the instantly claimed invention.

The disclosure of Venkatraman et al differs basically from the claimed invention, with the understanding that the claimed steps are not required to be performed in a sequential fashion, in that the content of water removal, although not expressly disclosed, is generic to the claimed water removal content and therefore necessarily implies that any amount of water removal, including the claimed content of water removal, would have been operable within the scope of patentee's invention and with a reasonable expectation of success, absent a clear showing of criticality for such clearly commensurate in scope with the claimed invention. As to the remaining process parameters per the dependent claims, the disclosure of Venkatraman et al is generic to these parameters which necessarily implies that any process parameters, including the claimed process parameters, would have been operable within the scope of patentee's invention and with a reasonable expectation of success. Venkatraman et al is provided by virtue of 102(e).

While Venkatraman et al do not expressly recognize the generation of a "bio-catalyst" from the disclosed process, motivation in the prior art does not have to be the same as that for the claimed invention as provided for under the guise of In re Kemps, 30 USPQ2d 1309(Fed. Cir. 1996). Moreover, the formation of the here recited bio-catalyst would merely follow as a necessary incident to the selection of the recited steps based solely on the motivation or suggestion

provided in Venkatraman et al. It would be reasonably expected that a phase separation of the polyvinyl alcohol solution of Venkatraman et al , as modified, would occur since the process parameters and components of Venkatraman et al , as modified, are essentially the same as the claimed process parameters and components and in the absence of the USPTO to have at its disposal the tools and facilities deemed necessary to make physical determinations of this sort.

As to the sequence of steps, the selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results (In re Burhans, 154 F.2d 690, 69 USPQ, 330 (CCPA 1946) & Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959)).

Response to Arguments

8. Applicant's arguments filed 11/15/04 have been fully considered but they are not persuasive.

Relative to Charmot et al & Venkatraman et al----- It is urged and maintained that the instantly claimed invention is obvious within the meaning of 35 USC 103 (a) over Charmot et al and Venkatraman et al as per reasons clearly stated in the Grounds of Rejection supra. The crux of Counsel's arguments appears to hinge on "the mere recitation of adding polyvinyl glycol and polyvinyl alcohol in these references does not cause the phase separation as recited in the pending Claims" and that the Affidavit of the inventor, Dr. Klaus Dieter Vorlop, filed herewith and incorporated by reference establishes this fact on the record.

To this end and with all due respect to the opinion of Counsel, the Declaration is one of opinion from an interested party and is given little or no probative value. The conclusory statement in the Declaration that "phase separation does not occur in any solution described in either of the references" is not found to be of substantial evidentiary value.

I. >< TO BE OF PROBATIVE VALUE, ANY OBJECTIVE EVIDENCE

SHOULD BE SUPPORTED BY ACTUAL PROOF

Objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See, for example, In re De Blauwe, 736 F.2d 699,705, 222 USPQ 191, 196 (Fed. Cir. 1984) ("It is well settled that unexpected results must be established by factual evidence." "[A]ppellants have not presented any experimental data showing that prior heat-shrinkable

articles split. Due to the absence of tests comparing appellant's heat shrinkable articles with those of the closest prior art, we conclude that appellant's assertions of unexpected results constitute mere argument."). See also In re Lindner, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972); Ex parte George, 21 USPQ2d 1058 (Bd. Pat. App. & Inter. 1991).

II. >< ATTORNEY ARGUMENTS CANNOT TAKE THE PLACE OF EVIDENCE

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.

As to the process steps being performed in a sequential fashion, the selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results (In re Burhans, 154 F.2d 690, 69 USPQ, 330 (CCPA 1946) & Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959)).

Counsel is herein advised that a rejection under 35 USC § 112, 2nd paragraph, in the future, can be avoided by correcting the dependency of claims 21 & 22 as they now stand dependent from a canceled claim (20). A rejection at this time is not being made since a viable rejection is outstanding on the record.

Conclusion

9. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Judy M. Reddick whose telephone number is (571) 272-1110. The examiner can normally be reached on 6:00 a.m. - 2:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Judy M. Reddick
Primary Examiner
Art Unit 1713

JMR
02.04.05